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February 20, 1999

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The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Cataplex F Tablets also contain extra iodine, for thyroid support.\*
- (2) Flaxseed oil can help support immune system functions. Essential fatty acids are important for proper functioning of the immune system and some studies indicate that flaxseed oil help maintain normal immune system function.\*
- (3) Flaxseed oil can help maintain cellular health. The oil contains alpha linolenic acid and is converted by the body into omega-3 oils, which are necessary for healthy functioning of cell membranes and maintenance of hair, nails, eye receptor cells, nerves, and brain tissue.\*
- (4) Flaxseed oil can help maintain a healthy flow of blood through the circulatory system. The alpha linolenic acid in flaxseed oil helps maintain the free flow of blood through the circulatory system in several ways.\*

These statements are made for a dietary supplement containing calcium lactate, defatted wheat germ, carrot powder, honey, vacuum dried bovine prostate, bovine liver powder, magnesium citrate, oat flour, bovine orchic glandular extract, glycerine, bovine liver fat extract, flaxseed oil extract, arabic and cellulose gum, potassium para-aminobenzoate, prolamine iodine, pyridoxal 5-phosphate, mixed tocopherols, ascorbic acid, and soy bean lecithin. The name of the product is Cataplex F Tablets®.

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The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

